

Notice of Allowability

Application No.

10/612,779

Examiner

Delia M. Ramirez

Applicant(s)

DENG ET AL.

Art Unit

1652

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 8/29/2007.
2. ☒ The allowed claim(s) is/are 1,4,8-10,12,21,25-41,45-47,49,50,52-54,57-61,219-226,228-239 and 243-252.
3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☐ All b) ☐ Some* c) ☐ None of the:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
 - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☒ Information Disclosure Statements (PTO/SB/08),
Paper No./Mail Date 8/16/07
4. ☐ Examiner's Comment Regarding Requirement for Deposit
of Biological Material
5. ☐ Notice of Informal Patent Application
6. ☐ Interview Summary (PTO-413),
Paper No./Mail Date _____.
7. ☒ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____.

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DETAILED ACTION

Status of the Application

Claims 1, 4, 8-10, 12, 21, 25-41, 45-47, 49-50, 52-54, 57-61, 219-226, 228-239, 243-252 are pending.

Amendment of claims 1, 4, 8-9, 12, 21, 36-41, 45-47, 49, 52, 54, 57-59, 219, 222, 228, 230-231, addition of claims 243-252, and cancellation of claims 2-3, 7, 11, 12-14, 17-20, 23, 55-56, 207-212, 218-227, 240-242 as submitted in a communication filed on 8/29/2007 is acknowledged.

In a telephone conversation with Mr. John Stolpa on 9/21/2007, an agreement was reached to amend claims 57-59, 223-224, 229 to place the claims in condition for allowance.

Examiner's Amendment

1. An extension of time under 37 CFR 1.136(a) is required in order to make an examiner's amendment which places this application in condition for allowance. During a telephone conversation conducted on 9/21/2007, Mr. John Stolpa requested an extension of time for 2 MONTH(S) and authorized the Director to charge Deposit Account No. 19-1970 the required fee of \$ 330.00 for this extension (\$ 330 = \$450 (2-month fee) – \$120 (1-month fee paid 8/29/07)) and authorized the following examiner's amendment. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

2. Please replace claims 57-59, 223-224, 229 as follows:

57. The method of claim 1, further comprising recovering an intracellular product from the microorganism selected from the group consisting of: intracellular glucosamine-6-phosphate, glucosamine-1-phosphate, N-acetylglucosamine-1-phosphate, and glucosamine.

58. A method to produce N-acetylglucosamine-6-phosphate, N-acetylglucosamine, glucosamine or glucosamine HCl by fermentation, comprising:

culturing in a fermentation medium a microorganism that is transformed with at least one recombinant nucleic acid molecule comprising a nucleic acid sequence encoding a glucosamine-6-phosphate acetyltransferase that has an amino acid sequence that is at least 95% identical to SEQ ID NO: 30; and

collecting a product produced from the step of culturing which is selected from the group consisting of N-acetylglucosamine-6-phosphate and N-acetylglucosamine;

and wherein the method further comprises a step selected from the group consisting of:

- (a) purifying N-acetylglucosamine from the fermentation medium;
- (b) dephosphorylating N-acetylglucosamine-6-phosphate to produce N-acetylglucosamine; and
- (c) treating N-acetylglucosamine to produce a glucosamine product selected from the group consisting of: glucosamine and glucosamine HCl.

59. The method of claim 58, wherein step (c) comprises hydrolyzing N-acetylglucosamine under acid and heat conditions or by enzymatic deacetylation.

223. The method of claim 229, wherein the *E. coli* further comprises a partial or complete deletion of the *nagA*, *nagB*, and *nagE* genes.

224. The method of claim 229, wherein the *E. coli* further comprises a partial or complete deletion of the *manXYZ* gene.

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229. The method of claim 222, wherein the *E. coli* further comprises a partial or complete deletion of the *pfkA* gene.

Reasons for Allowance

3. The following is an Examiner's statement of reasons for allowance. Although the prior art discloses methods to produce glucosamine by fermentation of a host cell which has been transformed with a nucleic acid encoding an *E. coli* glucosamine-6-phosphate synthase (U.S. Patent No. 6,372,457; cited in the IDS), the Examiner has found no teaching or suggestion in the prior art directed to a method to produce glucosamine, N-acetylglucosamine, or N-acetylglucosamine-6-phosphate by culturing a microorganism transformed with a nucleic acid encoding the *S. cerevisiae* glucosamine-6-phosphate acetyltransferase of SEQ ID NO: 30. Therefore, claims 1, 4, 8-10, 12, 21, 25-41, 45-47, 49-50, 52-54, 57-61, 219-226, 228-239, 243-252, directed to a process for the production of glucosamine, glucosamine HCl, N-acetylglucosamine, or N-acetylglucosamine-6-phosphate, wherein said method requires culturing a microorganism transformed with a nucleic acid encoding the polypeptide of SEQ ID NO: 30 or a polypeptide which has glucosamine-6-phosphate acetyltransferase and 95% sequence identity to the polypeptide of SEQ ID NO: 30, are allowable over the prior art of record.

Conclusion

4. Claims 1, 4, 8-10, 12, 21, 25-41, 45-47, 49-50, 52-54, 57-61, 219-226, 228-239, 243-252 are allowed.

5. Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

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6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Delia M. Ramirez whose telephone number is (571) 272-0938. The examiner can normally be reached on Monday-Friday from 8:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Ponnathapura Achutamurthy can be reached on (571) 272-0928. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-1600.



Delia M. Ramirez, Ph.D.
Primary Patent Examiner
Art Unit 1652

DR
September 25, 2007